

**Remarks**

Applicants request entry of the amendments, reconsideration of the application, and timely notice of allowability. Claims 1-17 are pending and claims 1-8, 12-14, and 17 are being examined.

The Title has been amended to more appropriately reflect the subject matter.

Solely for the Examiner's convenience in examining the elected claims and SEQ ID NOs, applicants have amended claim 1, without prejudice or disclaimer of any subject matter. Amended claim 1 recites the elected sequences. Applicants specifically reserve the right to seek allowance of the non-elected species and the remaining claims in this or related applications. No new matter enters through the amendments.

A marked-up copy of amended claim 1 is included as APPENDIX A, in accordance with 37 C.F.R. § 1.121. A clean copy of amended claim 1 also appears in APPENDIX A. None of the amendments limit the scope of applicants' invention. The amendment is made to indicate specifically the elected SEQ ID NO of this application and clarify the polypeptide or polynucleotide nature of some of the recited elements.

**I. The Rejection Under 35 U.S.C. § 101**

Claims 1-8, 12-14, and 17 stand rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks a specific and/or substantial utility or a well established utility (Paper No. 5 at pages 3-6).

Applicants respectfully disagree.

Table 1 at pages 10-13 of the specification lists the polynucleotides and polypeptides of the Sequence Listing and lists exemplary fragments from them. The sequence information includes a description that indicates the protein coding region (cds) where appropriate. Based on this information, in part, each sequence is assigned a transcription factor family association, as indicated by the parentheses under the column "GID No. (Family)." This association to a family follows from sequencing the polynucleotide and/or comparing the sequence to a known transcription factor family or domain, such as one of those listed at page 8, line 24, through page

9, line 11 of the specification. One of ordinary skill in the art recognizes that a transcription factor can be identified through the presence of a conserved domain. The document submitted herewith, Riechmann *et al.* Science 290:2105 (2000), as well as the references cited therein, confirm as much. Furthermore, one of skill in the art recognizes that altering transcription factor levels or expression levels in a transgenic plant can influence a number of traits.

At page 5 of Paper No. 5, the Examiner states that applicants "have not provided any evidence that these polypeptides actually function as transcription factors nor have they identified the specific genes that are regulated by these polypeptides." Applicants respectfully point out that the specification does indeed show that the recited polypeptides are plant transcription factors and shows how the expressed polypeptides, for example, alter a transgenic plant's ability to respond to environmental stresses, such as those occurring through pathogens. In one example, the polypeptide encoded by SEQ ID NO: 43 is analyzed in a plant when the plant is exposed to pathogens (*see* page 27, line 5 through page 29, Table 4). The experiments show that the SEQ ID NO: 43 protein-encoding sequence is induced by the *Fusarium* pathogen and by salicylic acid. Similarly, environmental stress response experiments show that the SEQ ID NO: 43 protein-encoding sequence is induced by hormones, cold, drought, and osmotic stresses (*see* page 29, line 5 through Table 5). Additionally, SEQ ID NO: 43 protein-encoding sequence is expressed at higher levels in seed compared to that of root (*see* page 30, line 5, through Table 6), indicating, among other things, that it can be used to alter the levels of seed compounds in transgenic plants.

Similar data exists for other sequences of the Sequence Listing. These data clearly indicate that and the sequences recited in the claims are involved in a number of stress-related mechanisms of plants. The identity of the genes these transcription factors can control is not necessary to determine that transcription factors can be used to manipulate plant traits. Since the sequences can be used to manipulate plant traits, such as stress responses, a specific utility for the sequences exists and would be understood by one of ordinary skill in the art.

Further proof that the sequences recited in the claims possess a patentable utility is shown in Table 7, at page 36 of the specification. Table 7 summarizes a panel of experiments performed by overexpressing the transcription factor-encoding sequences in a transgenic plant and analyzing the alteration in a number of different plant traits, for example, those traits that are

common throughout the plant kingdom. Table 7 specifically shows that the recited SEQ ID NO: 123, 125, 127, 43, 45, 47, 19, 37, 157, and 105, can each be used to modify a plant trait. Clearly, these are all specific uses and each plant trait listed is one that one of skill in the art would find commercially valuable and/or useful for one plant or another.

Whether or not applicants have disclosed exactly how the sequences of the claims or the SEQ IDs operate to modify the listed phenotypes or traits does not affect the fact that a patentable utility is clearly shown. There is no requirement that an applicant must know and disclose how a useful invention works at the molecular level. In contrast, the comments in Paper No. 5 refer repeatedly to "studying the properties of the protein itself," or similar language (*see* page 6, for example). However, the PTO has not shown that there is a total incapability of using the recited sequences for a useful purpose. Applicants have shown the successful use of the recited sequences. From the evidence in the specification and the evidence of what one of skill in the art understands in this field, the PTO will not be able to meet such a burden.

Applicants respectfully request the withdrawal of this rejection.

## **II. The Rejection Under 35 U.S.C. § 112, First Paragraph**

Claims 1-8, 12-14, and 17 stand rejected under 35 U.S.C. 112, first paragraph, as the specification allegedly fails to support a specific and substantial use and because one skilled in the art would not know how to use the claimed invention. Applicants respectfully disagree.

### **A. Enablement or "How to Use"**

As shown above, applicants have shown that the recited sequences of the claims modify useful traits in a transgenic plant. [Applicants hereby incorporate the comments addressing the § 101 rejection here by reference.] The type of techniques one of skill in the art could use to make and use an invention of this type is known in the art at the time the application was filed. The specification details a number of techniques one of skill in the art could employ to use the invention as claimed, including selecting sequences (pages 15-18, Table 7, and Example X), expressing the sequences and the producing transgenic plants (pages 18-23 and Examples IV-VI), and analysis of the traits of the transgenic plant (pages 27-31 and Example VIIIa, VIIIb, VIIIc). Applicants also show the successful use in, for example, the transgenic plants of Table 7. Any of this evidence surpasses the level that one of skill in the art would consider credible.

Thus, one of skill in the art would not doubt that the claimed invention could be used and would not doubt that the specification describes how to make and use the claimed invention.

Applicants respectfully submit that the rejection relying on the how to use or the enablement requirement of § 112, first paragraph, should be withdrawn.

#### **B. Written Description**

At page 7 of Paper No. 5, the PTO asserts that the claimed subject matter was not described in such a way as to reasonably convey possession of the claimed invention. Applicants respectfully disagree.

As noted above, the information in Table 1 includes specific fragments of the polynucleotides and polypeptides of the invention as listed in the sequence listing. One of skill in the art, who would have the full length sequence from the Sequence Listing, could easily make or produce any of the listed fragments. Furthermore, as specifically set out in the specification (*see, for example*, page 13, line 20 through page 18, line 9), one of skill in the art can modify, alter, or manipulated a given sequence through a number of well known techniques. Thus, one of skill in the art, who again would have the full length sequence or a fragment as starting material, could perform any number of know sequence modification or sequence identification techniques to possess any number of additional sequences. The specification also clearly describes how one of skill in the art can use assays, such as those listed in Examples IIa, IIb, or IIc, to identify plants with one or more altered traits. Thus, the specification clearly sets forth both specific sequences encompassed by the claimed invention beyond the SEQ ID NO sequences themselves, and clearly describes a number of other sequences that one of skill in the art possesses from the use of routine techniques employing the specific sequences, for example.

The PTO asserts (at page 8 of Paper No. 5) that "with the exception of the sequences corresponding to SEQ ID NO: 19, 37, 43, 45, 47, 105, 125, 127, and 157, the skilled artisan cannot envision the detailed chemical structure" of the sequences of the claims. The PTO then sites to cases, such as Amgen v. Chugai, where the applicant did not even possess the cDNA of the claimed invention encompassing a protein-encoding sequence. As pointed out above, applicants have specifically listed the cDNA and a number of fragments of the cDNAs in the Sequence Listing and Table 1. Applicants respectfully submit that the PTO has overlooked these specific descriptions, which encompass protein-encoding sequences or cDNA and not merely the

name "cDNA."

Furthermore, the type and scope of the structures immediately envisioned does not ignore the ability of one of skill in the art. Here, one of ordinary skill can do more than merely read sequences from a page. For example, once one of skill in the art possesses the cDNA, a number of immediately available and routine modifications to the cDNA are clearly envisioned by one of skill in the art. For example, with the cDNA, numerous vectors can immediately be envisioned containing the cDNA sequence. Some of these vectors include site-specific mutation capabilities through the use of well know techniques employing PCR amplification. IN addition, the specification at pages 14-15 and at Table 2 details a number of techniques for making substitutions, deletions, and insertions, for example. Thus, one of skill in the art immediately envisions the same type of modified structures noted in the specification and referred to above. To require specific listings of every sequence encompassed by a claim would essentially require applicants in this area to submit voluminous Sequence Listings encompassing every envisioned modification and use of the sequences.

Applicants have clearly described more that the "name cDNA itself" (*see* page 9 of Paper No. 5). Recognizing this fact and applying the appropriate standard and logical facts applicable in this art, applicants have indeed fulfilled the written description requirement for the claimed invention.

Applicants respectfully request withdrawal of this rejection.

### **III. The Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-8, 12-14, and 17 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner noted that part (a) and part (d) of amended claim 1 appear to recite the same group. Applicants have amended claim 1 to more clearly identify the polypeptide and polynucleotides recited. The Markush language of the new claims conforms with that suggested by the Examiner at page 10 of Paper No. 5.

Applicants respectfully request that this rejection be withdrawn.

#### IV. The Rejection Under 35 U.S.C. § 102

Applicants note at the outset that the GenBank documents cited for each of the rejections below appear to relate to partial nucleotide sequences that do not contain the entire protein coding sequences of the SEQ IDs of the claims. Some of these sequences probably represent ESTs for completely different plant genes or proteins and, from the content of these documents, none of them have been expressed in a plant. Accordingly, applicants amended claim 1, where the polynucleotides and polypeptides have been clarified in each of the sub-parts of the claim, is not anticipated by any of these sequences.

Claims 1 and 5 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Rounsley *et al.* (GenBank Acc. No. B29089). Applicants respectfully traverse the rejection. This sequence does not anticipate applicants amended claim 1, and the claims dependent thereon, as, *inter alia*, it appears to be merely a fragment of a gene that has not been expressed in a plant.

Claims 1 and 5 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Newman (GenBank Acc. No. T43527). Applicants respectfully traverse the rejection. This sequence does not anticipate applicants amended claim 1, and the claims dependent thereon, as, *inter alia*, it appears to be merely a fragment of a gene that has not been expressed in a plant.

Claims 1 and 5 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Newman (GenBank Acc. No. H76020). Applicants respectfully traverse the rejection. This sequence does not anticipate applicants amended claim 1, and the claims dependent thereon, as, *inter alia*, it appears to be merely a fragment of a gene that has not been expressed in a plant.

Claims 1 and 5 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Newman (GenBank Acc. No. T14116). Applicants respectfully traverse the rejection. This sequence does not anticipate applicants amended claim 1, and the claims dependent thereon, as, *inter alia*, it appears to be merely a fragment of a gene that has not been expressed in a plant.

Claims 1 and 5 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Newman (GenBank Acc. No. AI100243). Applicants respectfully traverse the rejection. This sequence does not anticipate applicants amended claim 1, and the claims dependent thereon, as, *inter alia*, it appears to be merely a fragment of a gene that has not been expressed in a plant.

These rejections are in error and applicants respectfully request their withdrawal.

**V. The Rejection Under 35 U.S.C. § 103**

Claims 1, 5, and 13-14 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Newman (GenBank Acc. No. H76020) in view of Newman *et al.* Applicants respectfully disagree.

As noted above, the Newman GenBank sequence is at best a fragment of a gene that has not been expressed in a plant. Thus, the sequence cited itself does not teach or suggest applicants' amended claim 1. Applicants have shown in their specification that the recited SEQ IDs of the claims can be used to alter a plant phenotype or trait. Before applicants disclosure, it may have been "obvious to try" to express the sequences and look for altered phenotype, but that is not the standard for obviousness. Furthermore, the reasoning in Paper No. 5 points to nothing to indicate why one of skill in the art would be motivated to look for altered plant phenotypes from what is at best a partial gene sequence of the Newman GenBank submission. It would have been clear to one of skill in the art that the sequence was not a full length cDNA or protein encoding region.

Accordingly, whether or not it would have been obvious to try to express the Newman GenBank sequence in a plant, the rejection offers no reason for expecting that the partial sequence would alter a plant phenotype.

Applicants submit that this rejection is in error.

**VI. Conclusion**

Applicants believe that this application is now in condition for allowance. If the Examiner believes that prosecution might be furthered by discussing the application with Applicant's representative, in person or by telephone, we would welcome the opportunity to do so.

Applicants have provided for an extension of time above. No additional extension of time fees, requests for extension of time, petitions, or additional claim fees are believed to be necessary to enter and consider this paper. If, however, any extensions of time are required or any fees are due in order to enter or consider this paper or enter or consider any paper accompanying this paper, including fees for net addition of claims, applicants hereby request any extensions or petitions necessary and the Commissioner is hereby authorized to charge our

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Deposit Account # 50-1129 for any fees. If there is any variance between the fee submitted and any fee required, including the extension of time fee and fee for net addition of claims, the Commissioner is hereby authorized to charge or credit Deposit Account No. 50-1129.

Respectfully submitted,  
**Wiley Rein & Fielding LLP**

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Appendix A



APPENDIX A

**Claim 1. (marked-up version)** An isolated polynucleotide comprising a nucleotide sequence selected from the group consisting of: (a) a nucleotide sequence encoding a polypeptide comprising [a] an amino acid sequence selected from the group consisting of SEQ ID Nos: 20, 38, 44, 46, 48, 106, 124, 126, 128, and 158 [2N-1, where N= 1-85]; (b) a nucleotide sequence encoding a polypeptide comprising a sequence selected from SEQ ID Nos: 20, 38, 44, 46, 48, 106, 124, 126, 128, and 158, [2N-1, where N+ 1-85;] including substitutions, deletions or insertions; (c) [a nucleotide sequence encoding a fragment from a polypeptide of (a) or (b); (d)] a nucleotide sequence comprising a sequence selected from SEQ ID Nos: 19, 37, 43, 45, 47, 105, 123, 125, 127, and 157; [1-88; (e)] (d) a nucleotide sequence having at least 40% identity with a nucleotide sequence of (a) [or (b)], (b) or (c); [(f)] (e) a nucleotide sequence having at least 60% identity with a nucleotide sequence of [(c); (g)] (a), (b) or (c); (f) a nucleotide sequence comprising at least 15 consecutive nucleotides of a polynucleotide sequence encoding an expressed plant polypeptide of SEQ ID NOs: 20, 38, 44, 46, 48, 106, 124, 126, 128, and 158 [SEQ ID NOs 2N-1, where N+1-85]; and [(h)] (g) [a nucleotide sequence that hybridizes to a sequence encoding a polypeptide] the complement of (a), (b) or (c)[ under stringent conditions].

**Amended Claim 1.** An isolated polynucleotide comprising a nucleotide sequence selected from the group consisting of:

- (a) a nucleotide sequence encoding a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 20, 38, 44, 46, 48, 106, 124, 126, 128, and 158;
- (b) a nucleotide sequence encoding a polypeptide comprising a sequence selected from SEQ ID NO: 20, 38, 44, 46, 48, 106, 124, 126, 128, and 158, including substitutions, deletions or insertions;
- (c) a nucleotide sequence comprising a sequence selected from SEQ ID NO: 19, 37, 43, 45, 47, 105, 123, 125, 127, and 157;
- (d) a nucleotide sequence having at least 40% identity with a nucleotide sequence of (a), (b) or (c);

- (e) a nucleotide sequence having at least 60% identity with a nucleotide sequence of (a), (b) or (c);
- (f) a nucleotide sequence comprising at least 15 consecutive nucleotides of a polynucleotide sequence encoding an expressed plant polypeptide of SEQ ID NOs: 20, 38, 44, 46, 48, 106, 124, 126, 128, and 158; and
- (g) the complement of (a), (b) or (c).